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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,845	01/26/2006	Jadwiga Bienkowska	ARS-113	2205

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EXAMINER	
MACFARLANE, STACEY NEE	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
07/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,845	BIENKOWSKA ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. All previously presented claims, Claims 1-56, have been cancelled, Claims 57-82 have been newly added as requested in the amendment filed on April 14, 2008. Following the amendment, claims 57-82 are pending in the instant application and will be examined upon their merits in the instant Office Action.

Sequence compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence identification has been provided for the amino acid sequences presented throughout the specification as "SCS0009" and the splice variants thereof, termed SCS0009-SV1 through SCS0009-SV5. Figures 1-6, 13-15 and 22-24 of the instant specification also contain amino acid or nucleic acid sequences that are not identified by a sequence identifier, as required by 37 C.F.R. § 1.821 through 1.825. The instant specification will need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04. In the case that these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present

in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see for example page 28. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 57-82 are rejected under 35 U.S.C. 101 because the claimed invention, an isolated polypeptide comprising: SEQ ID NO:2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10; is not supported by either a substantial asserted utility or a well-established utility.

The pending claims have been reviewed in light of the Revised Utility Guidelines, Vol. 64, Number 244, December 21, 1999, MPEP section 2107.

The Examiner is using the following definitions in evaluating the claims for utility.

"Specific"-A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial"-A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible"- Credibility is assessed for the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established"-a specific, substantial and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material alone or taken with the knowledge of one skilled in the art.

The claims are directed to a composition of matter comprising an isolated polypeptide that comprises an amino acid sequence of that recited in SEQ ID NO:2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO:8, SEQ ID NO:9 or SEQ ID NO:10.

On page 3, the specification states that the invention is based upon the identification of an Open Reading Frame (ORF) in the human genome encoding a novel Preadipocyte factor-1-like polypeptide, which will be referred to as SCS0009, and five other splice variants were identified by homology: SCS0009-SV1, SCS0009-SV2, SCS0009-SV3, SCS0009-SV4 and SCS0009-SV5.

As stated in section 2 above, the specification lacks proper sequence identifiers as required by 37 C.F.R. § 1.821 through 1.825 for each of SCS0009, SCS0009-SV1, SCS0009-SV2, SCS0009-SV3, SCS0009-SV4 and SCS0009-SV5. In the interest of compact prosecution, it is assumed that these relate in some way to SEQ ID NO:2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, but it should be

noted that the exact relationship between the polypeptides of the claims and those of the specification cannot be determined.

The specification goes on to assert utilities for these polypeptides based upon domain organization. Pages 50-53 of the specification, indicate putative roles for SCS0009, SCS0009-SV1, SCS0009-SV2, SCS0009-SV3, SCS0009-SV4 and SCS0009-SV5 such as they "may interact with integrin cell surface receptors, which are involved in cell adhesion" or "may act as integral SCS0009 antagonist in vivo" (emphasis added). Thus, the asserted functions of the polypeptide are merely hypothetical and based upon domain homology. The art generally acknowledges that function cannot be predicted based on structural similarity to a protein in the sequence databases (for review see, Skolnick et al., *Trends Biotechnol.* 18:34-39, published 2000).

The specification then teaches "metabolic endocrinology assays suitable for exploration of the biological relevance of protein function", which is an explicit recitation of further experimentation in order to test functional activities of the polypeptides of the claimed inventions. None of the teachings with regard to the asserted utilities meet the requirement of substantial real-world utility. Instead, they are invitations for further research to identify or reasonably confirm a "real world" context of use for the claimed polypeptides. Furthermore, since there is no specific utility for the polypeptide SCS0009, any asserted utility for splice variants thereof (SCS0009-SV1 through –SV5) is purely speculative.

Claims 57-82 are also rejected under 35 U.S.C. 112, first paragraph. Specifically,

since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 57, 64-69 and 77-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claim 57 recites "an active variant of SEQ ID NO:2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10 ...said active variant prevents the terminal differentiation of preadipocytes". Claims 64-69 and 77-82 are dependents claims that do not further limit the "variants", and are therefore included in the rejection. The claims do not require that the "active variants" possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of molecules merely defined by function and the instant specification fails to describe the entire genus of molecules that are encompassed by these claims.

8. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is unclear that Applicant is in possession of specific examples of "variants" because, as stated in section 2 above, it is undeterminable how the sequences within the disclosure relate to those identified within the claims. The claims, however, are drawn to "active variants" of polypeptides, and are thus, not limited to specific molecules with known structure.

9. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claim is a recitation of activity ("prevents the terminal differentiation of preadipocytes"). There is not even identification of any particular portion of a structure that must be conserved for the required activity. As stated above, it is not even clear what molecules within the specification are "active variants" as the specification does not provide a complete or partial structure and fails to provide a representative number of species for the recited genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

10. In *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, the court clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed structure of the claimed genus of active variants of SEQ ID NO:2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of identifying activity. Adequate written description requires more than a mere recitation of activity as part of the invention and a reference to assay methods for screening for said activity (pages 5-53 of the specification). The compound itself is required. See *Fiers v Revel*, 25 USPQ2d 1601 at 1601 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

11. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification only provided for the bovine sequence.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649